

HEALTH-CHEM DIAGNOSTICS, LLC

3341 S.W. 15th Street – Pompano Beach, FL 33069 - USA – Phone: (954) 979-3845 – Fax: (954) 979-7997
Website: www.healthchemdiagnostics.com

HEALTHCHECK®

Nitrite In Urine

Urinary Tract Infection Screening Test

FOR IN VITRO DIAGNOSTIC USE ONLY

FOR USE OUTSIDE THE BODY

Please read the entire insert before performing the test. If you have any questions, call the HealthCheck Help Line at 1-800-482-2907.

ABOUT THE TEST

The URI-TEST Nitrite in Urine detects nitrite in urine. Nitrite indicates the presence of certain bacteria that are commonly associated with Bladder/Urinary Tract Infection. Normally, urine is sterile (no bacteria) and therefore no nitrite is present. The test depends upon the conversion of nitrate (derived from the diet and usually present in urine) to nitrite by the action of bacteria in urine. By performing the test yourself at home, you may detect a possible urinary tract infection, sometimes before symptoms are noticed.

Any pink color that develops on the Sensor Pad indicates a positive reaction and means that you have nitrite in your urine. You should immediately consult your physician. Your physician will make a diagnosis and can prescribe an appropriate course of treatment. If you have a negative result with no pink color appearing but are experiencing symptoms of a Bladder/Urinary Tract Infection, contact your physician immediately. The clinical symptoms of a Bladder/Urinary Tract Infection may include burning, frequent urge to urinate, cloudy urine, unpleasant urine odor, abdominal discomfort, fever and/or lower back pain.

PRECAUTION: THIS PRODUCT DETECTS NITRITE IN THE URINE FOR THE PURPOSE OF ALERTING YOU AND YOUR PHYSICIAN TO THE NEED FOR FURTHER EVALUATION. NITRITE MAY APPEAR IN URINE WHEN BACTERIA IS PRESENT IN THE URINE. ADDITIONAL TESTING IS NECESSARY TO CONFIRM POSSIBLE INFECTION AND DETERMINE PROPER MEDICAL ACTION. THIS TEST CANNOT BE USED BY ITSELF TO DIAGNOSE URINARY TRACT INFECTION OR DETERMINE TREATMENT.

Under certain conditions and when used properly this test can tell you if you have bacteria in your urine. Bacteria is an

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indication of Urinary Tract Infection. A normal or abnormal result with this test means very little by itself. It is only one piece of information your physician needs in order to treat you. You should talk to your physician any time that you have symptoms, even if your test result is negative.

CONTENTS OF THE KIT

- Nitrite Reagent Test Strips
- Plastic Collection Cups
- Color Chart
- Product Instructions

Test Strips are ready to use from the package and are completely disposable. The Test Strips are stable when stored at room temperature until the expiration date as stated on the package.

PROPER USE AND STORAGE

DO NOT OPEN THE PACKAGE IN A STEAMY BATHROOM.

- Open the foil package and remove the Nitrite Test Strip. Do not open until ready to use.
- Do not touch the Sensor Pad.
- Do not let the Test Strip come in contact with any liquid prior to use.
- Store kit in a dry place below 86°F (30°C). Do not store in the refrigerator.
- Do not re-use Test Strip.
- Discard Test Strip after use.

DIRECTIONS FOR USE

For most accurate results:

- DO NOT OPEN IN A STEAMY BATHROOM.
 - Use your first morning urine or urine sample after last urination.
 - Use an accurate watch or clock to measure timing of test.
1. Collect fresh urine in the clean plastic cup included. Collected urine should be tested as soon as possible. If sample is not tested immediately, urine can be stored in the refrigerator for up to 8 hours. If you store your urine, before testing let the urine stand at room temperature for 15-20 minutes.
 2. Remove the Nitrite Test Strip from the individual foil package.
 3. Examine the Test Strip prior to use. The Sensor Pad should be a buff (white/beige) color. Discard if Sensor Pad is damaged or discolored.
 4. Completely immerse the test area of the Test Strip in fresh urine for 1 second.
 5. After wetting the Test Strip with urine, tap the Test Strip against the side of the container.
 6. Wait 60 seconds. Compare the color of the Test Sensor Pad to the Color Chart provided.

IMPORTANT: WHEN READING, HOLD THE TEST STRIP CLOSE TO THE COLOR BLOCKS AND MATCH COLOR CAREFULLY. IMPORTANT NOTE: IGNORE COLOR CHANGES THAT OCCUR AFTER 3 MINUTES.

READING THE RESULT:

NORMAL/NEGATIVE: After 60 SECONDS, compare the Sensor Pad to the Color Chart provided. If no pink color appears, the **TEST RESULT IS NEGATIVE**. No pink color indicates that there is no detectable nitrite in your urine and that the test is negative. A negative result does not always mean that you have no bacteria present in your urine. There are several possible causes of false negative results including:

- Bacteria causing the infection does not produce nitrite.
- When urine has not been retained in the bladder long enough (an estimated 4 hours), the bacteria may not have sufficient time to reduce nitrate to nitrite.
- Use of antibiotics or Vitamin C.
- When dietary nitrite is absent, even if the organisms containing reductase are present and incubation in the bladder is ample, the absence of nitrite in urine may be due to unusual dietary conditions, (i.e. a diet free of vegetables).

IMPORTANT: WHEN READING, MATCH THE SENSOR PAD TO THE COLOR CHART PROVIDED. IF THE TEST IS NEGATIVE AND YOU CONTINUE TO EXPERIENCE ANY ABNORMAL SYMPTOMS, YOU SHOULD SEE YOUR PHYSICIAN.

ABNORMAL/POSITIVE: Wait 60 SECONDS and compare the Sensor Pad to the Color Chart provided. If any shade of pink color appears on the Sensor Pad, the **TEST RESULT IS POSITIVE**. The appearance of colors other than pink may be related to the presence of certain dietary or therapeutic dyes or blood in your urine. Ignore any color changes that occur after 3 minutes. If you have any questions about the results, please call the HealthCheck Help Line at 1-800-482-2907.

IMPORTANT: WHEN READING, MATCH THE TEST STRIP TO THE COLOR CHART ENCLOSED. IF YOU SEE ANY PINK COLOR ON THE TEST STRIP THIS IS CONSIDERED A POSITIVE TEST FOR NITRITE. NITRITE IS PRODUCED BY BACTERIA THAT COMMONLY CAUSE BLADDER/URINARY TRACT INFECTIONS. CALL YOUR PHYSICIAN. IF YOUR RESULT IS POSITIVE, IT IS IMPORTANT TO SEE YOUR PHYSICIAN AS SOON AS POSSIBLE, IF THE TEST IS NEGATIVE AND YOU CONTINUE TO EXPERIENCE ANY ABNORMAL SYMPTOMS, CONTACT YOUR PHYSICIAN.

GUIDELINES FOR USE

The majority of urinary tract infections are caused by “Gram Negative” bacteria, which changes nitrate, normally found in urine, to nitrite. Therefore, a positive URI-Test Nitrite in Urine test can mean that you have bacteria in your urine. It is recommended that you use this test whenever you suspect a possible urinary tract infection. Your physician may recommend use of the test following treatment of urinary tract infection to confirm the success of the treatment.

EXPECTED VALUES

Normally, there is no detectable nitrite in urine. If no pink color is observed on the Sensor Pad, as compared to the Color Chart provided, the test is negative. A positive result is indicated by a color change, from white to any shade of pink (i.e. the Sensor Pad is a darker pink than the negative block on the Color Chart). A positive result indicates you have nitrite in your urine. Nitrite is produced by bacteria that commonly cause a urinary tract infection.

Negative: No pink color

Positive: Any shade of pink

After testing, write down your test results so that you can discuss them with your physician. If you have a negative test result and you continue to have symptoms of a

Bladder/Urinary Tract Infection, contact your physician immediately. The clinical symptoms of Bladder/Urinary Tract infections may include burning, frequent urgency to urinate, cloudy urine, unpleasant urine odor, abdominal discomfort, fever and/or lower back pain. If you have any questions concerning your test result, please contact the HealthCheck Help Line at 1-800-482-2907,

LIMITATIONS

1. The URI-Test Nitrite in Urine is not a conclusive test for infection. Positive results MUST be confirmed by your physician.
2. Large amounts of Vitamin C fruit juices (Ascorbic Acid) and/or antibiotic therapy can lead to lower or false negative results.
3. False negative or false positive results, or the occurrence of a color other than pink may indicate the presence of certain dietary, or therapeutic dyes or blood in the urine.
4. False negative results could be related to infection by a bacteria that does not change nitrate to nitrite.

5. False negative results could be related to frequent urination (urine not held in the bladder for at least 4 hours) where the bacteria is unable to change nitrate to nitrite.

PRODUCT PERFORMANCE: STUDIES HAVE BEEN DONE TO CONFIRM THE PERFORMANCE OF THE URI-TEST NITRITE IN URINE. 101 SPECIMENS WERE TESTED BY BOTH A LABORATORY TECHNICIAN AND A CONSUMER. URI-TEST NITRITE IN URINE WAS COMPARED TO ANOTHER PRODUCT USED FOR THE DETECTION OF NITRITE. WHEN COMPARED TO A SIMILAR PRODUCT THE ACCURACY OF THE URI NITRITE IN URINE WAS 91% WHEN READ BY A LABORATORY TECHNICIAN AND 93% WHEN READ BY A CONSUMER.

Accuracy of the URI-TEST Nitrite in Urine: Results based on the user when test results are compared to a similar product:

Consumer Accuracy: 93%

Lab Tech Accuracy: 91%

Manufactured in the USA by:

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CUSTOMER HOT-LINE - CALL 1-800-482-2907

Certified ISO/CMDCAS 13485:2003



FM77504 - Quality Award

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